

Notice of Allowability	Application No.	Applicant(s)	
	09/996,265	YOUNG ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 22, 2003.
2. ☒ The allowed claim(s) is/are 128-134, 137-163 and 165-203.
3. ☒ The drawings filed on 28 November 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/22/2003</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Margaret Brivanlou on March 19, 2004.

The application has been amended as follows:

IN THE SPECIFICATION:

Page 4, line 31, after "SYNAGIS®," insert --palivizumab,--.

IN THE CLAIMS:

Cancel claims 135, 136 and 164.

Replace claims 128-134 with the following:

--Claim 128. A method of preventing a respiratory syncytial virus (RSV) infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a variable light (VL) domain having an amino acid sequence of SEQ ID NO: 11, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 129. A method of preventing a RSV infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a variable heavy (VH) domain having an amino acid sequence of SEQ

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ID NO: 48, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 130. The antibody of claim 128 further comprising a VH domain having an amino acid sequence of SEQ ID NO: 48.

Claim 131. A method of preventing a RSV infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VH complementarity determining region (CDR) 1 having an amino acid sequence of SEQ ID NO: 10, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 132. A method of preventing a RSV infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VH CDR2 having an amino acid sequence of SEQ ID NO: 19, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 133. A method of preventing a RSV infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VH CDR3 having an amino acid sequence of SEQ ID NO: 20, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 134. A method of preventing a RSV infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of

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an antibody comprising a VL CDR1 having an amino acid sequence of SEQ ID NO: 39, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.--

Replace claim 163 with the following:

--Claim 163. The method of claim 134, wherein the antibody further comprising a VL CDR3 having an amino acid sequence of SEQ ID NO: 6.--

Replace claims 172-174 with the following:

--Claim 172. A method of preventing a respiratory syncytial virus (RSV) infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5, a VLCDR3 having an amino acid sequence of SEQ ID NO: 6, and a VH CDR1 having an amino acid sequence of SEQ ID NO: 10, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 173. A method of preventing a respiratory syncytial virus (RSV) infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5, a VLCDR3 having an amino acid sequence of SEQ ID NO: 6, and a VH CDR2 having an amino acid sequence of SEQ ID NO: 19, wherein the antibody immunospecifically

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binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.

Claim 174. A method of preventing a respiratory syncytial virus (RSV) infection or a symptom thereof, said method comprising administering to a mammal in need thereof a dose of an effective amount of an antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5, a VLCDR3 having an amino acid sequence of SEQ ID NO: 6, and a VH CDR3 having an amino acid sequence of SEQ ID NO: 20, wherein the antibody immunospecifically binds to a RSV F antigen and the effective amount of the antibody results in an effective neutralizing titer of an antibody.--

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance:

The amendment to the specification was made to include the generic name of SYNAGIS®, which is palivizumab.

The amendments to claims 128-134 were made to clarify the identity of the antibody that immunospecifically binds to RSV F protein. The antibodies that immunospecifically bind to RSV F protein according to claims 128-134 are capable of eliciting neutralizing antibody titers effective to prevent a RSV infection or a symptom thereof. Table 2 sets forth examples of monoclonal antibodies and Fab fragments having the regions comprising SEQ ID NO: 11, 48, 10, 19, 20 and 39. These constructed antibodies were tested for neutralization ability in microneutralization tests in Example 7. The specification clearly demonstrates that the administration of antibodies and Fab fragments having the regions of SEQ ID NO: 11, 48, 10,

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19, 20 and 39, to cotton rats reduce RSV titers and prevent RSV infection (see page 129, Table 14 and Table 2).

The amendments to claims 129 and 130, changing SEQ ID NO: 254 to SEQ ID NO: 48, were made to correct the SEQ ID NO of the VH domain.

The amendment to claim 163 was made to correct the SEQ ID NO of the VL CDR3.

The amendments to claims 172-174 were made to correct claim dependencies and incorporate all the limitations of the cancelled claim, since claim 164 was cancelled in this examiner's amendment. Further, claims 172-174 were amended to recite that the antibody binds the RSV F protein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Claims 128-134, 137-163 and 165-203 as amended above, are allowable.

Note that the IDS submitted December 22, 2003 was considered. The citation DQ was lined through because it is not in conformance with MPEP 609. Reference DQ lacks a date. Upon further review of copy of the reference provided by Applicant, no date could be determined.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

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for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (571) 272-0896. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
March 19, 2004

James C. Housel
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